K131411

5. 510(k) Summary

1. Submitter

Jilin Coronado Medical Ltd.
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Jilin City, China
Tel: 86-432-63529555
Establishment Registration Number: 3009718176

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SEP 2 6 2013

2 Device

Trade name:	CoSeal™ Arterial Compression Band
Common Name:	Compression Device
Classification Name:	clamp, vascular
Classification:	Class II
Regulation Number:	870.4450

3 Predicate Device

The predicate devices used to determine substantial equivalence are the TR Band™ Radial Compression Device marketed by Terumo Cooperation (K070423), and the Air-Band™ Radial Compression Device (K122405) marketed by MAQUET Medical Systems USA.

4 Device Description

The CoSeal™ Arterial Compression Band ("CoSeal Band") is a hemostasis device which works by providing controlled compression on the radial artery without completely occluding blood flow or significantly compressing other structures. It consists of a Velcro belt attached with a balloon, and an injection port. The device also includes a separated syringe (inflator) for injecting air.The CoSeal band is a device that is sterile, for single use, and has a 24month shelf life with one adjustable wristband for different patient size.

5 Intended Use

The CoSeal™ Arterial Compression Band is a compression device that indicated to assist hemostasis of the radial artery after a transradial procedure, the device is designed to compress the radial artery puncture site while maintaining site visibility and a secure fit around the wrist, minimizing the loss of blood.

6 Comparison of Technological Characteristics

Compared with the predicate devices, it shows that the technological characteristics of the proposed device such as operational principle, performance characteristics, and sterilization are identical or substantially equivalent to the currently marketed predicate devices.

Device Comparison Table

The tables attached below listed the differences and similarities between CoSeal™ Band and *TR ™ Band and Air Band (*Predicate Device) in several aspects.

Comparison of General Information

Item	**CoSeal™**	***TR Band™***	***Air Band™***	**Comments**
Manufacturer	Jilin Coronado Medical Ltd	Terumo Cooperation	MAQUET	-
Intended Use	The CoSeal™ Arterial Compression Band is a compression device to assist haemostasis of the radial artery after transradial procedure, while minimizing the loss of blood.	Equivalent	Equivalent	Equivalent
Operational Principle	It's used to fixed on the top of the puncture site after the PCI procedure. The balloon is expansion by pressuring. It'll continually pressure on vascular, then achieve the hemostasis.	Equivalent	Equivalent	Equivalent
Sterilization Method	ETO	ETO	Irradiation	Similar

Comparison of Design and Specifications

Sub-component	**Function**	**CoSeal™**	***TR Band™***	***Air-Band™***
Wristband length	Fix the device on the puncture site	28cm	24/29cm	26cm
Wristband adjustability		Adjustable	Equivalent	Equivalent
Balloon	Hold the pressure	Transparent	Equivalent	Equivalent

Balloon number	for the needed amont on the puncture site	Single	Double	Single
Balloon volume		18ml, maximum 20ml	Normal 13ml, maximum 18ml	7cc (7ml)
Accessory	syringe	Similar Design	Similar Design	Similar Design
Luer check valve	luer valve on the end of the fill tube enables a luer lock syringe to be connected to inflate and deflate the balloon with air to provide compression	Similar Design	Similar Design	Similar Design
Flexible tube (PU tube)	Passage for the air go through into the balloon	Similar Design	Similar Design	Similar Design

Comparison of materials

Component	**CoSeal™**	***TR Band™***	***Air Band™***	**Comments**
Wristband	Fabric (Velcro (Polyester and nylon blend material))	Elastoplasts	Non-woven textile	Similar
Balloon	Medical grade Polyvinylchloride	Elastoplasts	Medical grade polyurethane	Similar
Syringe	Polypropylene	Equivalent	Equivalent	Equivalent
Flexible tube	polyurethane	Elastoplasts	Polyvinylchloride	Similar
Adhesives	MD UV light Curing Adhesives	Similar	Similar	Equivalent

7 Performance Data

The results of the performance testing demonstrated the safety and effectiveness of the CoSeal™ Arterial Compression Band is equivalent to the predicate devices.

Performance Testing included:

- Leak test
- Performance test
- Packaging Performance
- Product Stability (Shelf Life)
- Product Sterilization
- Biocompatibility Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 26, 2013

Jilin Coronado Medical Ltd.
c/o Ms Tianya Ma
Regulatory Specialist
9 South-west Circle Road
Fengman Economic Development Zone
Jilin City, China

Re: K131411
Trade/Device Name: CoSeal™ Arterial Compression Band
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: August 22, 2013
Received: August 27, 2013

Dear Ms. Ma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K131411

4. Indications for Use Statement

510(k) Number (if known):_____ Device
Name: CoSeal™ Arterial Compression Band

The CoSeal™ Arterial Compression Band is a compression device that indicated to assist hemostasis of the radial artery after a transradial procedure. the device is designed to compress the radial artery puncture site while maintaining site visibility and a secure fit around the wrist, minimizing the loss of blood.

Prescription Use ___×___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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